



September 15, 2021

Vascular Solutions, Inc.  
Sara Coon  
Sr. R.A. Associate  
6464 Sycamore Court  
Minneapolis, Minnesota 55369

Re: K052232

Trade/Device Name: Pronto V3 Extraction Catheter  
Regulation Number: 21 CFR 870.5150  
Regulation Name: Embolectomy catheter  
Regulatory Class: Class II  
Product Code: QEZ

Dear Sara Coon:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 28, 2005. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075,  
[Gregory.Oconnell@FDA.HHS.gov](mailto:Gregory.Oconnell@FDA.HHS.gov).

Sincerely,

Gregory W. O'Connell -S  
Digitally signed by  
Gregory W. O'Connell -S  
Date: 2021.09.15  
09:09:58 -04'00'

Gregory O'Connell  
Assistant Director  
DHT2C: Division of Coronary  
and Peripheral Intervention Devices  
OHT2: Office of Cardiovascular Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 28 2005

Vascular Solutions, Inc.  
c/o Ms. Sara L. Coon  
Senior Regulatory Affairs Associate  
6464 Sycamore Court  
Minneapolis, MN 55369

Re: K052232  
Pronto V3™ Extraction Catheter  
Regulation Number: 21 CFR 870.5150  
Regulation Name: Embolectomy catheter  
Regulatory Class: II  
Product Code: DXE  
Dated: August 16, 2005  
Received: August 17, 2005

Dear Ms. Coon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Ms. Sara L. Coon

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

*Donna R. Zuckerman*

*[Signature]* Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications For Use Statement

510(k) Number: K052232

Device Name: Vascular Solutions Pronto V3™ Extraction Catheter

Indications for Use:

The Pronto V3 Extraction Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels of the arterial systems.

Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lockner  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K052232

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## Appendix A: Summary of Safety and Effectiveness

**Common/Usual Name:** Embolectomy Catheter

**Product Trade Name:** Pronto V3™ Extraction Catheter

**Classification Name:** Unclassified  
Product Code, DXE

**Manufacturer:** Vascular Solutions, Inc.  
6464 Sycamore Court  
Minneapolis, Minnesota 55369

**Establishment Registration:** 2134812

**Contact:** Sara L. Coon  
Senior Regulatory Affairs Associate  
(763) 656-4300 phone  
(763) 656-4250 fax

**Performance Standards:** No performance standards have been developed under section 514 for this device.

### Device Description:

The Pronto V3 extraction catheter is a dual lumen catheter with related accessories. The extraction lumen allows for the aspiration and removal of embolic material (thrombus/debris) using the included syringe, extension line and stopcock. The catheter has a rounded distal tip with a protected, sloped opening of the extraction lumen to facilitateatraumatic advancement of the catheter into the blood vessel and maximize extraction of emboli/thrombi through the extraction lumen. Incorporated within the catheter distal tip is a non-blood contacting radiopaque marker for fluoroscopic visualization. The catheter is a monorail design with a distal flexible region with stiffness along the shaft tapering to a stiff proximal region. The distal segment of the catheter is coated with a hydrophilic coating to lubricate the catheter for ease of insertion. The catheter has an approximate outer diameter of 0.065 inches, allowing delivery through standard 6Fr. guide catheters. The smaller wire lumen of the catheter is able to accommodate guide wires that are ≤ 0.014" in diameter. The catheter will be available in working lengths of 40 to 145 cm with the length changes being made in the proximal rail section. The proximal end of the

catheter incorporates a standard luer adapter to facilitate the attachment of the catheter to the included extension line, stopcock, and syringe. A 74 micrometer filter basket (not identified in the schematic below) is included for assistance in filtering the blood removed during the procedure for laboratory analysis of thrombus.

**Intended Use:**

The Pronto V3 Extraction Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels of the arterial systems.

**Summary of Non-Clinical Testing:**

Testing conducted included assessments of the design verification of the Pronto V3 Extraction Catheter along with biocompatibility assessments. The results of this battery of tests confirmed the suitability of the Pronto V3 Extraction Catheter for its intended use.

**Summary of Clinical Testing:**

No clinical evaluations of this product have been conducted.

**Predicate Devices:**

The Pronto V3 Extraction Catheter is similar in intended use to the Vascular Solutions, Inc. Pronto Extraction Catheter and the Medtronic Export™ Aspiration Catheter.

**Conclusions:**

The Pronto V3 Extraction Catheter is substantially equivalent to the Pronto Extraction Catheter and the Export Aspiration Catheter. The testing performed confirms that the Pronto V3 Extraction Catheter will perform as intended.



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Sincerely yours,

*Bram D. Zuckerman*

*[Signature]* Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

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Enclosure

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Darina R. Lechner  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K052232

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